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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,432	04/21/2004	Saverio Carl Falco	BB1167B	7009

23906 7590 09/26/2005

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
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WILMINGTON, DE 19805

EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,432

Applicant(s)

FALCO ET AL.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election and amendment filed August 18, 2005. Applicant elects Group I and SEQ ID NO:3 encoding SEQ ID NO:4 without traverse. Claims 12-20 are pending and are examined in the instant application. Since SEQ ID NO:3 encoding SEQ ID NO:4 was first disclosed in Application No. PCT/US99/15809, Applicant has priority benefit of the filing date of July 13, 1999. This restriction is made FINAL.

Sequence Listing

2. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:3 and its corresponding amino acid sequence SEQ ID NO:4, it is unclear what region of SEQ ID NO:3 encodes SEQ ID NO:4. Clarification is required.

Specification

3. Applicant is required to update the status of parent priority Application No. 09/720384 on the first line of the specification. Correction is required.

Drawings

4. The drawings submitted April 21, 2004 are acceptable for examination.

Claim Rejections - 35 USC 101 Utility

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 12-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. The

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claimed invention does not meet the utility requirements under current utility guidelines for the following reasons. Applicant does not disclose that SEQ ID NO:3 encodes a complete protein; and SEQ ID NO:3 does not appear to contain a complete open reading frame since it does not begin with the start codon methionine. Thus, SEQ ID NO:3 appears to be a fragment of the sequence encoding the adenosine 5'-phosphosulfate kinase enzyme. Further, neither Applicant's disclosure nor the state of the prior art at the time the invention was made provides guidance as to where the catalytic domain(s) of Applicant's SEQ ID NO:4 is located. No empirical data are presented to verify that SEQ ID NO:3 or a nucleotide sequence encoding SEQ ID NO:4 encodes a protein having the asserted activity. While empirical data are not required, sequence alignment is generally useful in placing a protein in a particular class but does not replace verification of function. Moreover, while the complete protein is substantially useful in sulfate assimilation in plants (specification, p. 1), an incomplete protein without enzymatic activity would not have substantial utility. Table 4 (p. 17) shows that SEQ ID NO:4 has 52% sequence identity with a sequence obtained from *Catharanthus roseus*. However, it is unclear whether the prior art sequence used for sequence alignment with Applicant's SEQ ID NO:4 is a complete protein, and what the sequence identity would be if both the prior art sequence and Applicant's sequence are complete proteins. Since SEQ ID NO:3 encodes a partial protein and does not appear to contain the catalytic domain(s) necessary for enzymatic function, the utility for such a sequence would be lacking. It would also follow that sequences having less than 100% sequence identity to SEQ ID NO:4 would also lack utility for the same reasons.

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Additionally, there is no well-established utility for SEQ ID NO:3 and a sequence encoding SEQ ID NO:4. SEQ ID NO:3 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12-20 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining enzyme activity. Applicant provided no working examples or further guidance as to which region(s) of SEQ ID NO:3 are conserved domains necessary for protein activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated without undue experimentation. Accordingly, the claimed invention is not enabled.

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9. Claims 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having less than 100% sequence identity to SEQ ID NO:4. However, the translated amino acid sequence SEQ ID NO:4 appears to be only a partial sequence of a protein (see utility rejection above). SEQ ID NO:3, which encodes SEQ ID NO:4, is only a partial gene sequence and does not contain a complete open reading frame encoding a complete protein. However, the "comprising" language in the claims reads upon complete gene sequences having in common a nucleotide sequence encoding SEQ ID NO:4. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the complete structure of a gene encoding an adenosine 5'-phosphosulfate kinase protein based upon the disclosure of a partial sequence, absent further guidance. Accordingly, one skilled in the art would not recognize from Applicant's disclosure of SEQ ID NO:3 that Applicant is in possession of the complete gene encoding a complete protein.

The claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been

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disclosed. The claims also encompass adenosine 5'-phosphosulfate kinase proteins from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:3 isolated from *Zea mays*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants of other *Zea mays* plants, or the structure of adenosine 5'-phosphosulfate kinase proteins from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

10. No claim is allowed. SEQ ID NO:3 encoding SEQ ID NO:4 is free of the prior art. The closest prior art teaches a sequence from *Catharanthus roseus* having 52% sequence identity with Applicant's SEQ ID NO:4 (Table 4). It is understood by the Office the recited Clustal alignment method uses the default parameters set forth on page 17, lines 10-12 of the specification.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

09/17/05

A handwritten signature in black ink, appearing to read 'Phuong T. Bui', with a stylized flourish at the end.

Phuong T. Bui
Primary Examiner
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